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# HEALTH CARE NEWS

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HCN SPECIAL REPORT

**HOW EIGHT STATES DESTROYED THEIR INDIVIDUAL INSURANCE MARKETS**

PART 1 IN A SERIES p. 9

## Lessons from the Flu Vaccine Shortage

**by Conrad F. Meier and Joseph L. Bast**

Every year, influenza—"the flu"—invades the U.S., striking the elderly and the ill especially hard. Every year, the Food and Drug Administration (FDA) tries to determine in advance which strain of influenza is most likely to afflict the U.S., and then recommends the particular vaccine likely to be most effective in combating that strain.

Tommy Thompson

This year, a combination of errors and bad public policies resulted in a shortage of vaccine, with potentially life-threatening consequences. The shortage also prompted counter-

VACCINE p. 4

## *Report: TennCare "Not Financially Viable"*

**by Conrad F. Meier and Diane Carol Bast**

A management consulting firm hired to evaluate the financial viability of TennCare, the state's troubled Medicaid program, issued the first of a two-part report on December 11. The prognosis was bleak.

"Our assessment is that, even with current and planned improvement efforts and solid program management, TennCare as it is constructed today will not be financially viable" over the five-year evaluation horizon, concluded analysts for New York-based McKinsey & Company.

"TennCare will consume 36 percent of total state appropriations in fiscal year 2008 (up from 25 percent in 2003)," con-

TENNCARE p. 17

# Seniors Wary of New Medicare

**by Conrad F. Meier**

President George W. Bush praised the new Medicare legislation he signed into law on December 8, saying it represents a "victory for all of America's seniors."

But a CNN/USA Today/Gallup poll conducted just days before the bill's signing showed the nation's seniors are very sensitive to changes in Medicare …and wary of the new law's broad reform provisions.

According to the poll, conducted December 5-7, a small plurality of senior citizens over 65 supports the prescription drug benefits law. But there is more opposition than support among seniors for the broader changes in Medicare. Few senior citizens believe the Medicare reform measure will help them financially, and a majority feels the plan does not go far enough to help them cope with drug costs.

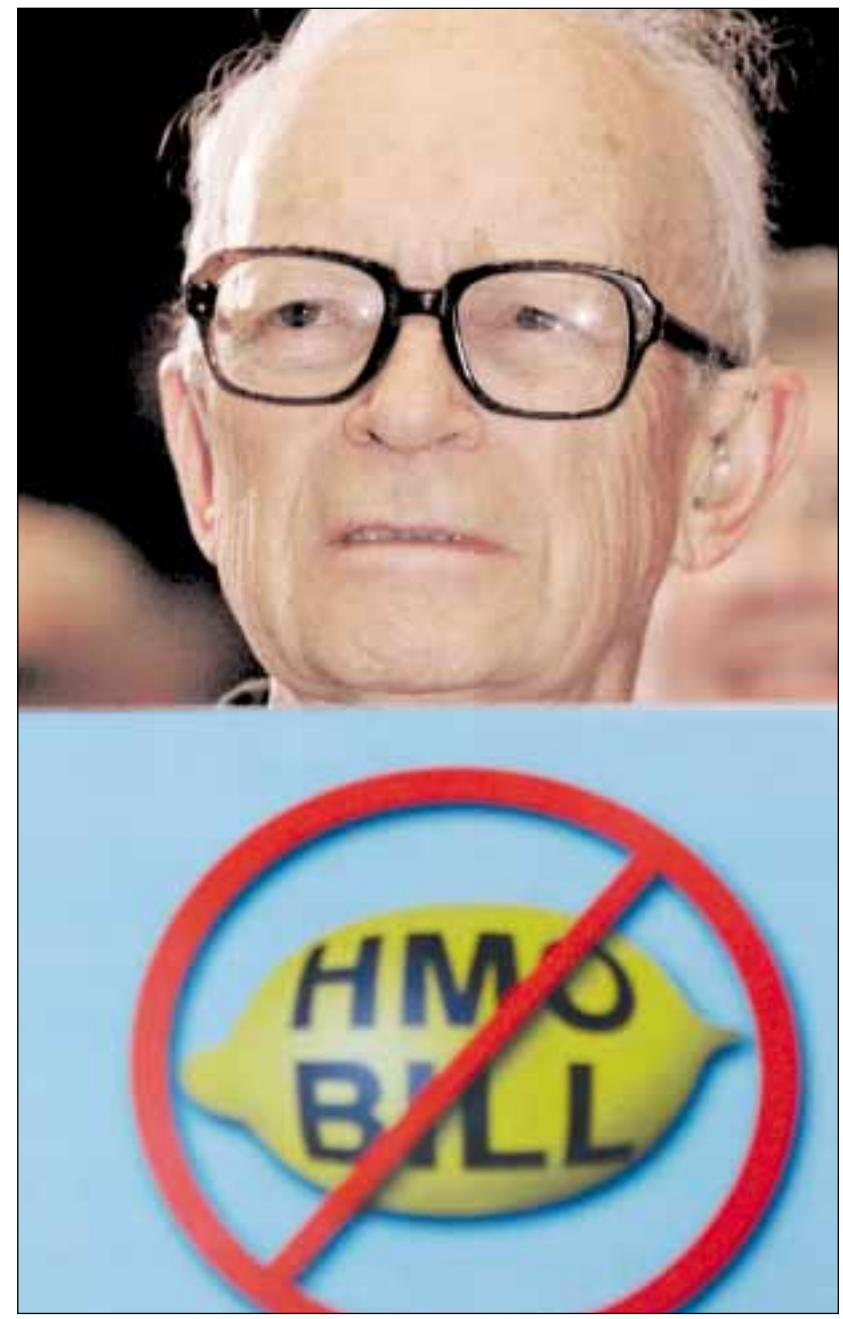
### Taking the Pulse

Previous Gallup polling found 73 percent of Americans aged 50 and older, and 84 percent age 65 and older, use prescription drugs. The average person 65 and older who uses prescription drugs pays out-of-pocket costs of $137 a month for drugs, or $1,644 a year.

Polling conducted in 2003 showed Americans of all ages support the general idea of a prescription drug benefit. A June Gallup Poll showed 76 percent support a bill that would "spend $400 billion over the next 10 years to create a new Medicare program that would help senior citizens pay for prescription drugs." Seniors and younger Americans were just as likely to approve. The Gallup results pretty much square with the findings of other polls.

But those polls were conducted before the details of the current

SENIORS p. 15




Getty

Gordon Allen, 84, of Gaithersburg, Maryland, listens to speakers at a rally of seniors against the Medicare Prescription Drug Act on Capitol Hill December 8, 2003.

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# CDHCC SPRING 2004

www.cdhcc.com

## March 29-31, 2004
## Las Vegas Hilton, Las Vegas, NV

In 2003, more than 1000 industry leaders gathered for the Consumer Directed Health Care Conference and Expo. Again in 2004, CDHCC will bring many of the countries top employer, health plan and provider community executives in an educationally rich and quality networking environment.

CDHCC is designed for employers, health plans, providers and policy makers. It focuses on providing a marketplace to express ideas about the market numbers, market trends and issues. Attendees are exposed to a wide assortment of topics from specific case studies, exploring the intricacies of health care, from national health care policies and the influx of the elderly, to the benefits of using decision support tools.

CDHCC will be co-located with the first Boomers Business Conference & Expo, a show focusing on the extraordinary purchasing power of a huge market segment. Shared keynote sessions and a shared exhibit hall will enhance the CDHCC experience for attendees.

### Program Tracks include:

**Employer Community** - Addressing the emerging developments and presenting case studies for employers wrestling with rising health care costs, productivity losses from health care related issues and the current standing of employees participating in consumer driven health models.

**Provider/Pharma Community** - Highlighting the key issues, from rising health costs and the quality of delivery to the impact of a more informed consumer/patient.

**Health Plan/Broker/Agent Community** - Featuring the latest health plan designs for health care consumers and employers.

**Technologies Transforming Healthcare and Retirement** - Focuses on the latest technologies impacting consumer driven health care and the emerging seniors market (boomers).

### Keynote speakers include:

- Tom Scully, Former Administrator, Center for Medicare/Medicaid Services
- Jeff Lemieux, Senior Economist, Progressive Policy Institute/Executive Director, Centrists.Org
- Doug Kronenberg, Chief Strategy Officer, Lumenos
- Neil Trautwein, Director of Employment Policy, National Association of Manufacturers
- Grace-Marie Turner, Founder, President & Trustee, Galen Institute, Inc.
- Greg Scandlen, Director of Center for Consumer Driven Health Care, Galen Institute, Inc.
- Bruce Goodman, CIO, Humana, Inc.
- Jack Wolf, VP, Hospital Corp. America (HCA)
- Bradford Holmes, Healthcare Research Director, Forrester Research, Inc
- Joe Coughlin PhD, Founding Director, MIT AgeLabs
- Wendy Borow-Johnson, SVP, Turner Media Group/President, Healthy Living Channel

### Keynote topics include:

- **Implications of HSA's on Consumer Directed Healthcare**
- **Implications of Recent Healthcare Reform for Consumers and Boomers**
- **Reform or Transform: Where To Next/Where Will We End Up**
- **Finding Common Ground (or Not) in CDH**
- **Where Is Consumer Directed Healthcare Headed/Considerations for the Boomers?**
- **Technology's Impact on the Consumers/Boomers Marketplace**
- **Implications of the Aging Workforce**

# Consumer Directed Health Care Conference & Expo

## Who Should Attend?

**Employer Community:**
- o **CEOs, COOs, CFOs**
- o **HR Benefit Consultants/Managers/Directors**
- o **HR Directors/Managers**

**Health Plan Community:**
- o **Health Plan Executives**
- o **Medical Directors**
- o **Medical and Disease Management Professionals**
- o **eHealth/IT Directors**
- o **Plan Design Managers**
- o **Brokers/Agents**
- o **Business Development Managers**

**Provider and Pharmaceutical Community:**
- o **Medical Directors**
- o **Physicians**
- o **Hospital and Health System Executives**
- o **Managed Care Contracting Executives**
- o **eHealth/IT Directors**
- o **Medical Group Directors**
- o **Practice, Office and Physician Relations Managers**
- o **Marketing and Business Development Managers**
- o **Pharma: Managed Care Marketing, Public Policy, Communications and PR, e-Business and e-Marketing**

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**Co-located with the Boomers Business Conference & Expo - www.boomersbusiness.com**

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# Supreme Court Takes Up Patients' Rights

Rep. Charles Norwood (R- Georgia)

**by Tom Bruderle**

The U.S. Supreme Court agreed in November to consider whether patients can bring suit against insurance companies and health plans when they refuse to pay for health care their doctors recommend.

The Court's decision to hear the case could be the culmination of the "patients' bill of rights" (PBOR) controversy that has swirled around Congress and engaged the lobbying efforts of the National Association of Health Underwriters, its members, and its allies for the past six years.

**Right to Sue?**

At issue in the two combined cases from Texas the Court agreed to examine is whether patients who believe they have been harmed have a right to sue their health plans in state courts for malpractice or some other tort. Or does the Employee Retirement Income Security Act of 1974 (ERISA) preclude such action by giving the federal government sole authority to regulate employee benefit plans?

It was precisely the issue of state versus federal responsibility for employee benefit plans that was the crux of patients' rights legislation. Although competing versions of the legislation were approved by each house in recent years, Congress never passed a bill.

In 2002, the U.S. Court of Appeals for the Fifth Circuit, located in New Orleans with jurisdiction over Louisiana, Mississippi, and Texas, ruled individuals could sue in state courts. The court said plan decisions to pay for a treatment are both insurance and medical in nature, thus insurance companies and plans could be found liable under state statutes enforcing health care standards.

**"[T]he Court agreed to examine whether patients who believe they have been harmed have a right to sue their health plans in state courts for malpractice or some other tort."**

In their appeal to the Supreme Court, Aetna Health and Cigna HealthCare of Texas claim their coverage decisions are about insurance, not medical care. Making carriers subject to state courts for benefit determinations would violate ERISA, which was designed to ensure uniformity in the regulation of employee benefit plans nationwide.

The introduction during the opening days of each new Congress of legislation allowing patients to bring suit against their employers' health plans has been as reliable as the cherry blossoms in Washington DC each spring. The passage of time, however, and the emergence of other health care issues have eclipsed PBOR.

The bill introduced in February 2003 by Representative Charles Norwood (R-Georgia) contained a provision creating an independent review panel for patients denied care by their health plan but, unlike past years, it contained no mention of liability. The lead cosponsor of previous PBOR legislation, Representative John Dingle (D-Michigan), said moving the most recent version of the bill in the absence of the liability language found in the past "would be like trying to move a car forward without the engine."

Oral arguments before the Supreme Court are expected early this year with a decision due in June or July.

*Tom Bruderle is vice president of congressional affairs for the National Association of Health Underwriters (NAHU). His email address is* **tbruderle@nahu.org**. *Reprinted with permission.*

# *Mental Health Parity on 2004 Agenda*

**by Tom Bruderle**

Senator Judd Gregg (R-New Hampshire), chairman of the Health, Education, Labor & Pensions Committee, and Senator Pete Domenici (R-New Mexico) are drafting compromise mental health parity legislation for consideration by the committee in early 2004. Details of the proposal were unavailable at press time.

Domenici and other supporters had hoped for a vote on the Senator Paul Wellstone Mental Health Equitable Treatment Act (S 486) in 2002, but Majority Leader Bill Frist (R-Tennessee) decided to move the bill through "regular order," that is, through Gregg's committee, rather than bring it directly to the Senate floor for debate and a vote.

Domenici is the lead sponsor of the bill, named after Senator Paul Wellstone (D-Minnesota), who died in a 2002 plane crash while campaigning for reelection. Among the bill's 66 cosponsors are all 49 Senate Democrats. Both Domenici and Wellstone led a bipartisan effort to enact mental health parity legislation in 2002.

Domenici's current bill would prohibit health plans from mandating higher copayments, deductibles, and coinsurance for mental health services. It would also reimburse for mental disorders identified in the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV), published by the American Psychiatric Association. Rep. Patrick J. Kennedy (D-Rhode Island) introduced a companion bill (HR 953) in the House, which has 242 cosponsors.

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# Vaccine

Continued from page 1

feiters to attempt to enter the vaccine market, an invasion which, if successful, could have been deadly.

**Central Planning**

Government officials made at least two apparent mistakes in planning for this year's flu season. The first was choosing to target the wrong flu virus.

The FDA committee that decides which vaccine to use was divided between those who favored a new vaccine against the Fujian strain of influenza, which would have required growing the virus in canine kidney cells and then transferring it to chicken eggs, and those who favored a vaccine that could be made using conventional methods but would provide less protection.

"This is the time for Americans to really step up to the plate and get vaccinated against influenza."
DR. JULIE GERBERDING
CDC DIRECTOR

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According to Dr. Sydney Smith, a family physician and publisher of MedPundit, the newer vaccine required a production method that "isn't FDA-approved. In the end, the other committee members decided it was better to stick with the approved method. ... That was in March. By December, the Fujian strain accounted for 75 percent of the influenza cases in the United States. And although so far it hasn't been any deadlier than usual, it has been more widespread."

The second mistake was by the Centers for Disease Control (CDC), which broke from past practices by recommending that everyone, regardless of age and risk status, be immunized. Dr. Smith quotes CDC Director Dr. Julie Gerberding saying, "This is the time for Americans to really step up to the plate and get vaccinated against influenza," and Secretary of Health and Human Services (HHS) Tommy Thompson saying, "There is plenty of vaccine to meet demand."

In fact, only 83 million doses had been produced, less than the number of seniors and persons with illnesses making them vulnerable to infection, and far less than the number of people who, frightened by the CDC and assured by HHS, lined up for vaccinations that were probably unnecessary.

Government agencies such as the CDC and HHS have institutional incentives to err on the side of being too conservative when facing risks. In this case, employees of the CDC put the risk to their own careers of approving a new method of producing vaccines that might produce negative side effects above the risk of producing a less-effective vaccine for millions of people. Staffers at HHS avoided the risk of being faulted for not taking the flu season seriously enough ...by causing a run on a vaccine they knew was in short supply.

The first lesson of the vaccine shortage, then, is that putting too much authority into the hands of a few government agencies is dangerous to public safety.

**Lawsuits and Liability**

Only three companies in the U.S. are licensed to produce the flu vaccine: Aventis Pasteur (Fluzone), Chiron Corp. (Fluvirin), and MedImmune Inc. (the nasal spray FluMist). If more companies made the vaccines, it is unlikely the supply would have been so short, or that more doses could not have been made on short notice. Why so few?

The number of vaccine manufacturers in the U.S. has dropped from 20 to only three during the past 15 years largely as a result of lawsuits filed on behalf of supposed victims of vaccine side effects. Vaccine makers have been under nearly constant legal assault by lawyers.

Most recently, personal injury lawyers have filed lawsuits against the maker of Thimerosal, a vaccine preservative that contains mercury, claiming the compound is responsible for the recent rise in cases of autism. However, researchers have studied repeatedly the possibility of a link and have found no evidence.

According to legal expert Peter Huber, 50 to 80 percent of the cost of most vaccines is liability insurance. The risk of losing such cases, and especially the risk of losing a class-action suit that could cost the industry hundreds of millions or even billions of dollars, has persuaded many companies to leave the vaccine marketplace.

The biotechnology industry has made it clear that the threat of lawsuits is keeping it from investing in new vaccines and medicines to meet the threat of bioterrorism, such as the deliberate spread of smallpox and anthrax. In a November 2002 letter to Sen. Tom Daschle (D-South Dakota), the president of the Biotechnology Industry Organization (BIO), Carl B. Feldbaum, wrote, "Without a clear understanding of liability protection, most of our companies, particularly the smaller, innovative companies, will be unable to contract to provide preventive therapeutics or products if it means putting the future of their businesses at risk."

The second lesson from the vaccine shortage, then, is that until lawsuit abuse is checked, drug companies will not take the necessary risks involved with producing a sufficient supply of vaccines, much less invest in finding the next generation of life-saving vaccines.

**Importing Counterfeits**

In late December, U.S. health officials prevented the sale of a half-million doses of an alleged flu vaccine that turned out to be, according to the *New York Times*, "a foreign product of unknown quality and content, not licensed for use in this country." The bogus vaccine had been offered for sale to the Florida Health Department.

Several foreign countries manufacture flu vaccines, and U.S. officials said they were not yet sure where the counterfeit drugs were being made. Investigations into the incident are ongoing.

"The Food and Drug Administration (FDA) has received reports of potential distribution of unlicensed influenza vaccine in the United States," the agency reported in a statement issued December 23. "The Agency is aggressively working with state health authorities and the Centers for Disease Control and Prevention (CDC) to investigate the source and quality of influenza vaccine being made available through unusual suppliers."

"We're concerned about people attempting to bring in unlicensed material, claiming to have licensed vaccine, from sources that are either suspect or unclear," said Steven Masiello, director of the Office of Compliance and Biologics Quality in the FDA's Center for Biologics Evaluation and Research. "The demand is bringing out individuals who are trying to make a quick dollar" and might also inspire criminals to make counterfeit vaccine, added Masiello.

The third and final lesson from the vaccine shortage is that ensuring the quality of the U.S. drug supply is a challenge that grows stronger every day. Importing drugs from foreign countries breaches the country's first line of defense against counterfeit and adulterated drugs, with potentially deadly consequences.

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# Drug Importation Remains Illegal

**by Conrad F. Meier**

The Medicare Prescription Drug Improvement and Modernization Act of 2003, signed by President George W. Bush in December, contains language allowing prescription drug importation from Canada ... with an important safety caveat: The Department of Health and Human Services (HHS) must certify that drugs can be safely imported before imports will be allowed. As was true of importation-allowing provisions in legislation signed by past administrations, the language is expected to act as an effective legal barrier to drug importation schemes.

HHS has opposed the legalization of importation, which HHS officials believe would increase the risk of counterfeit and tainted prescriptions entering the U.S. drug supply. Even Health Canada, that country's counterpart to HHS, has stated it cannot guarantee the safety of drugs sold out of Canada.

The Medicare reform measure, which allows imports from Canada only, requires HHS to certify the safety of reimportation, all but assuring the practice will remain illegal. The decision to give HHS veto power over importation has spurred proponents to turn attention back to stand-alone legislation sponsored by Rep. Gil Gutknecht (R-Minnesota).

The Gutknecht bill would allow importation from Food and Drug Administration (FDA)-approved facilities in 25 industrialized countries and would require the use of technology to prevent counterfeiting.

Safety concerns have kept the American Medical Association and other physician groups from supporting drug importation as a way to improve access to medications.

"Those who choose to ignore [the importation ban] do so at their own risk," said Jeff Trewhitt, spokesman for the Pharmaceutical Research and Manufacturers of America. "The United States already has a small domestic counterfeit problem, but it cannot compare to the scale of international counterfeiting rings that would gain a foothold if borders were opened by reimportation."

### Risk Is Real

Just before passage of the Medicare reform measure, the Senate Commerce, Science and Transportation Committee examined the importation issue. The committee's chair, Senator John McCain (R-Arizona), said, "Demand for lower prices should not lead us to sacrifice the health and safety of our citizens. That is why any legislation that permits the freer importation of pharmaceuticals must contain safeguards that protect American consumers from tainted or counterfeit prescription drugs."

"Even if it isn't apparent, the harm is still real," said Carmen A. Catizone, executive director of the National Association of Boards of Pharmacy. "Injuries resulting from patients receiving wrong or counterfeit drugs may not manifest themselves in the health care system until sometime later, when the patient's condition worsens and requires emergency treatment or hospitalization," he noted.

It's also an issue of knowing exactly where the drugs are coming from, Trewhitt pointed out. "Prescriptions from Canada may largely be safe and genuine, but many counterfeiters use the Canadian postal system, which is not well monitored, to funnel bogus and expired drugs into the U.S. market," he explained.

John Graham, director of health and pharmaceutical policy research at the Fraser Institute in Vancouver, Canada, also thinks in terms of safety. Said Graham, "Drug manufacturers have strong incentives to play a significant role in preventing counterfeiting, other types of fraud, and activities that threaten the integrity of the distribution chain that connects factories to customers.

"But," warned Graham, "they only have that incentive if you allow them to manage the distribution chain and to keep the markets differentiated. If you say to the manufacturer it is against the law for him to have input into the distribution chain, and it is against the law for him to profit from managing the distribution chain, then the manufacturer loses all interest, or a significant amount of his interest, in combating the counterfeiting problem."

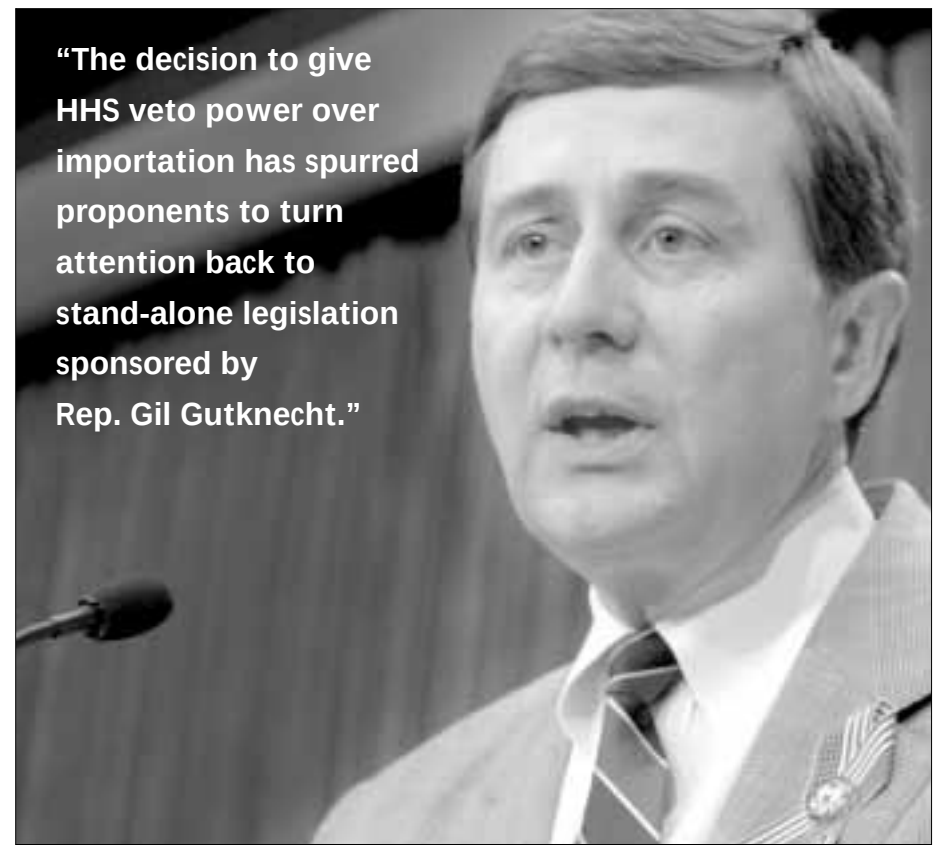
### In Harm's Way

To date, 12 states continue to ignore public safety and the law, demanding the federal government's permission to import drugs for state entitlement programs like Medicaid and state employee benefit plans. So far, warnings from the FDA have kept states from importing prescription drugs themselves, but they are finding ways to circumvent the law.

Minnesota, for example, has established a special office and Web site to guide patients though the purchase of prescriptions from registered Canadian pharmacies. Illinois State Senator Chris Lauzen (R) has helped launch a similar Web site in that state.

Illinois Governor Rod Blagojevich (D) said the new Medicare law gives HHS the authority to waive the rules against bringing in drugs from outside the country in order to establish a pilot program. Shortly before Christmas, Blagojevich sent a letter to HHS Secretary Tommy Thompson requesting such a waiver and asking for a decision in 30 days. The response was almost instant, and Blagojevich was told HHS will not authorize his pilot program.

Bill Pierce, spokesperson for HHS, said Thompson cannot certify the safety of imported prescription drugs because they "pass outside the FDA's scrutiny during manufacture or shipment." Pierce added, "Canada has great standards, but we have U.S. standards. Our law is very specific. It's not a 'will not.' It's a 'cannot'."


"The decision to give HHS veto power over importation has spurred proponents to turn attention back to stand-alone legislation sponsored by Rep. Gil Gutknecht."

Roll Call Photos

## FDA: Cost of Enforcement Would Exceed Benefits of Importation

As millions of Americans turn to Canada and even borderless Internet drug stores for less-expensive medicines, the FDA's pharmacy affairs director, Tom McGinnis, said it would take hundreds of millions of dollars to set up a legal, safe program to import the medicines. Despite pressure from Congress, state governors, and municipal officials, he insisted the FDA would never rely on Canada's safety assurances for drugs shipped out of that country.

In the international mail facility at New York's John F. Kennedy International Airport, packages of confiscated prescription drugs are stacked floor-to-ceiling. The thousands of such illegal mail-order drugs stopped at America's entry points, however, are a small fraction of the multimillion-dollar business that federal regulators are struggling to control.

McGinnis told the Associated Press the FDA would not piggyback its inspections on the Canadian system because the United States inspects drug manufacturers around the world, while Health Canada often relies on inspections done by the drug maker's host country. "We want to see everything with our own eyes. We've never accepted inspection results from another country," said McGinnis.

The FDA's stubborn stand on illegal cross-border drug sales sets the tone for a Health and Human Services study on the safety of Canadian drug imports. The study, required by the Medicare reform measure President George W. Bush signed in December, was included as a way to appease lawmakers bent on legalizing imported drugs.

McGinnis, who was surveying the illegal take at Kennedy Airport in late December, said, "Anything can be done with enough resources and the authority to do inspections. ... You're talking about a lot of resources, and when is cost going to outweigh benefit?"

*— C.M.*

FDA Associate Commissioner Peter Pitts said importation is a "gimmick" and "not a solution to a difficult problem" because the practice "leads to unapproved, possibly counterfeit, mislabeled, expired, improperly packaged, illegal, unsafe medications."

*Conrad F. Meier is managing editor of* Health Care News. *His email address is* **meier@heartland.org**.

**INTERNET INFO**

Video clips and transcripts of presentations delivered at an October 23, 2003 National Symposium on Drug Importation are available on The Heartland Institute's Web site at **http://www.heartland.org/Article.cfm?artId=13270.**

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Register online today! www.boomersbusiness.com

# It's time to retire your old ideas about "Aging Boomers"!

It's true that the first of the Boomers will be turning 65 in just a few short years. And it's true that the Boomer generation represents an extraordinary share of this country's spending power ***... an aggregate income estimated at $4.1 trillion!*** But those who sit and wait for the Boomers to gracefully turn into "Seniors" will be waiting a long time. ***Boomers may be growing older, there's not going to be anything graceful about it!*** This is not a group that speaks with one voice, but with a chorus of well-educated and highly developed opinions and a load of market savvy. This is not a market segment. This is ***the*** market!

## Boomers Business is YOUR Business

From March 29-31, 2004, we're rolling out the big guns to help you jump start your move to capture the Boomers' business. The highest level of thought leaders from around the country will assemble to discuss and share the strategic planning necessary to face this marketing challenge. Representatives from the public and private sectors, from package goods, health care, travel and financial services, from agencies and their clients ... will come for the insightful sessions, the networking, and the Expo Hall. The Boomers Business Conference & Expo will be **co-located with the spring Consumer Directed Health Care Conference & Expo (CDHCC)** and will share keynote addresses, the "Technologies Transforming Healthcare and Retirement" track and a common exhibit hall.

## Learn why your marketing strategy for Boomers may be stuck in the "middle ages"

More than ***100 expert speakers*** representing all segments of the industry will be on hand at the Boomers Business Conference & Expo. The most relevant issues will be addressed by more than ***38 sessions in four tracks:***

***Lifestyle Considerations*** - how boomers are dealing with their elderly parents, post-college children, their jobs and plans for retirement. Learn how travel, real estate, package goods and other companies are rethinking their strategies.

***Healthcare Considerations*** - Leaders in the industry will discuss innovative ways to assess wellness, health, insurance, and other key healthcare related concerns of the boomers as they age.

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# Evaluating the Pros and Cons of Importation

## *National Symposium on Drug Importation offers seven good reasons to import drugs from Canada, and eight good reasons not to*

*Managing Editor's note: On October 23, 2003, The Heartland Institute hosted a National Symposium on Drug Importation featuring elected officials from Illinois and policy experts from Canada and major U.S. think tanks. Joseph Bast, president of The Heartland Institute (publisher of* Health Care News*), delivered concluding remarks, from which this essay is drawn.*

**by Joseph L. Bast**

Whether or not to allow drugs to be imported from Canada is not a simple issue. Over the course of the conference, I heard seven good reasons why we should import drugs from Canada, and eight good reasons why we should not.

### The Case for Importation

1. Many people are paying too much for their prescription drugs or can't afford to buy them at all. The state of Illinois can't afford the 10 percent and 12 percent annual increases in the amount they are spending on drugs. We know that drugs in Canada are cheaper, so it's an obvious opportunity to cut costs and possibly, for some of these people, save lives.

2. Canadian drugs are safe. Critics cannot point to people who have died from drugs that were imported from Canada. They say, "well, just wait until the next news cycle," but that hasn't happened yet. Right now, a strong case can be made that current levels of importation are safe.

3. Consumers should be free to buy a legal product from a willing seller. As a libertarian myself, I think that should be true in a wide array of areas. Why should we make an exception in this case?

4. International trade is a source of tremendous consumer benefit. Any argument for trade restrictions has to overcome the strong presumption in favor of free trade. How is this product so different from nearly all other products that it justifies a ban on international trade?

5. There is nothing in the U.S. Constitution that says the federal government should protect me from Canadian drugs. If it's not in the Constitution, it's not within the power of the federal government to do it. It should be delegated to state and local governments. They should be able to make their own choices on this issue.

6. Senator Chris Lauzen pointed out what he thought were excessive profits on the part of prescription drug companies, which he thought indicated there was a lack of competition in this market. If that's true, what we've got now is not really a free market. Companies that want to engage in price discrimination ought to be required to enforce resale contracts themselves.

7. Senator Lauzen and some of our audience members said repeatedly that price discrimination is simply unfair. Lauzen said it is wrong that some people are being charged twice or three times as much as other people. People are right to be angry about it, and elected officials are being called on to do something about it.

### The Case Against Importation

1. Consumer safety trumps consumer choice in this case. Why? Because "let the buyer beware" doesn't work when you're dealing with prescription drugs. Even an expert can't distinguish a safe and effective pill from a counterfeit pill or a substitute, contaminated, or expired pill. And once they have entered the country, tracking and removing these poisons would be extremely costly.

2. Cheap imports mean drug companies are going to have to cut their prices; they're going to have less money to put into research and development. That would dry up the funds that make a very innovative, productive industry possible. The result would be lost jobs and fewer new lifesaving drugs.

3. Importation means importing Canada's price controls. Throughout history governments have tried to put price controls on various products. It has never worked. It's led to distortions, evasions, black markets, waste, and inefficiency. The same thing will happen if we attempt to impose price controls on drugs.

4. Drug importation is the first step toward greater government control over the prescription drug industry. Right now the government exercises massive control and interference in other parts of the health care system. The drug industry is probably the freest part of the health care industry. Importation would be the first step toward bringing the drug industry into the same kind of restrictions, regulations, and price controls that have made a mess out of the rest of the health industry.

5. Importation violates intellectual property rights, patents in particular. Importation says that if a patent has expired or isn't honored in any country, it doesn't have to be honored in the United States. This vitiates any patent protection. Without strong patent protection, you will see less innovation and fewer lives saved by new drugs.

6. Importation is not a long-term solution. Companies will simply export fewer drugs to Canada. Since Canada's market is very tiny compared to the U.S. market and since it imports most of the drugs it needs for its own residents, within a year or two the price differential would disappear, much to the disadvantage of Canadians, and we will have gained very little.

7. There are alternatives. Right now, 5.5 million patients get free medicine from discount cards provided by major pharmaceutical manufacturers. All of the major drug companies have discount card programs that give drugs at very low prices or even for free to people who are senior citizens and low-income. They also give substantial discounts to Medicaid programs and to state employees.

8. Litigation looms. If you work for the state of Illinois or are a retired state employee or if you're on Medicaid, under Governor Blagojevich's plan, you would be receiving drugs imported from Canada and not inspected by either Health Canada or the FDA. If one of those drugs is found to be counterfeit or contaminated or expired or in some other way a threat to your health, who do you hold accountable? Do you sue the guy who sold it to the state? Do you sue the state for allowing these drugs to be provided to you? Do you sue the original manufacturer for failing to prevent the fraud? It becomes very confusing, and in confusing situations, I have noticed that lawyers make tons and tons of money and the victims typically get very little.

*Joseph L. Bast is president of The Heartland Institute. His email address is* **jbast@heartland.org**.

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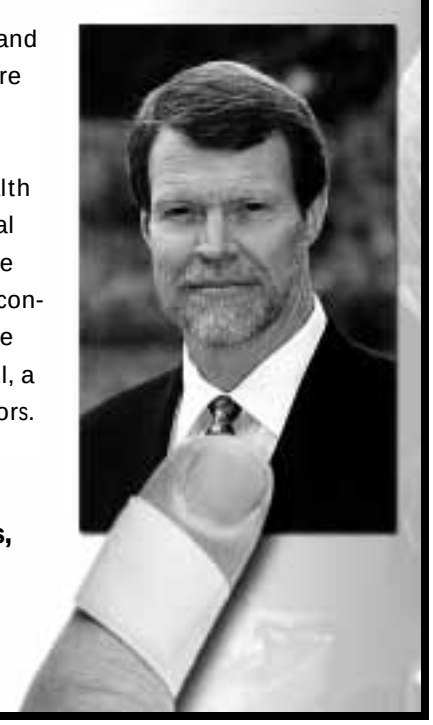
Merrill Matthews Jr., Ph.D., is a Heartland Senior Fellow specializing in health care policy and director of The Council for Affordable Health Insurance. Dr. Matthews is past president of the Health Economics Roundtable for the National Association for Business Economics, the largest trade association of business economists, and health policy advisor to the American Legislative Exchange Council, a bipartisan association of state legislators.



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OPEN LETTER **TO CONGRESS**

# Economists Warn of Dangers of Drug Importation, Price Controls

**drafted by Milton Friedman, Ph.D.**

We are deeply concerned about proposed legislation to remove pharmaceutical companies' ability to control the importation of their products. The goal of this legislation will be to reduce prices in the American market by imposing other nations' price controls on us. If this attempt succeeds, American consumers would get the short-term windfall of lower prices, but they would end up unnecessarily suffering and living shorter lives—because promising new therapies would be delayed or not even developed. Even the threat of price controls reduces the incentive to develop new drugs.

The ideal solution would be for other wealthy nations to remove their price controls over pharmaceuticals. America is the last major market without these controls. Imposing price controls here would have a major impact on drug development worldwide, harming not only Americans but people all over the world. On the other hand, removing foreign price controls would bolster research incentives. In addition, most new drugs are developed by American firms, and price controls would harm those firms and their employees.

Drug price controls are more difficult to remove than other price controls. Controls on oil and other products often tend to be limited or short-lived, as voters eventually object to the resulting shortages and distortions. The effects of drug price controls, however, are far more difficult to observe because they mainly affect medicines that haven't been invented yet.

Even if people were to realize that price controls are preventing new drugs from being developed, undoing the effects of those controls would be a difficult task. Customers would have to pay higher prices for years before they saw benefits. Firms would have to be convinced that controls would not be reimposed as soon as their new drugs are released.

For these reasons, we urge Congress to abandon attempts to peg U.S. drug prices to controlled prices in other nations.

*Dr. Milton Friedman, who received the 1976 Nobel Memorial Prize for economic science, has been a senior research fellow at the Hoover Institution since 1977. He is also the Paul Snowden Russell Distinguished Service Professor Emeritus of Economics at the University of Chicago, where he taught from 1946 to 1976, and was a member of the research staff of the National Bureau of Economic Research from 1937 to 1981. Friedman was awarded the Presidential Medal of Freedom in 1988 and received the National Medal of Science the same year.*

*This open letter was first published on November 20, 2003 by Tech Central Station (***http://www.techcentralstation.com***) and is reprinted here with permission.*

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INTRODUCTION TO A SERIES

# Destroying Insurance Markets

*How community rating and guaranteed issue have destroyed the individual insurance market in eight states*

**by Joseph L. Bast**

During the early 1990s, state legislators and insurance regulators faced growing public concern over two health insurance problems. The first was rising insurance premiums threatening to price middle- and low-income consumers out of the private insurance market. The second was "job lock," the inability of people to take their health insurance with them when they changed jobs.

Each state adopted a different package of legislation and reforms. Some created high-risk pools that subsidized the premiums of people with health problems that made them uninsurable; some passed tort reform to reduce the cost of unnecessary litigation; some offered tax credits to the uninsured and unemployed.

**"Imposing community rating and guaranteed issue on the individual health insurance market causes premiums to rise, not fall, and makes it more difficult, not easier, for the uninsured to find affordable coverage."**

Many states adopted regulations requiring health insurance companies to accept anyone who applied for coverage and charge everyone within each group the same rates regardless of their age, gender, lifestyle choices, or health status. These regulations, called guaranteed issue and community rating (see sidebar), were intended to force healthy people to subsidize less-healthy people, and to make it easier for people without health insurance to get back into the system.

Eight states—Kentucky, Maine, Massachusetts, New Hampshire, New Jersey, New York, Vermont, and Washington—imposed community rating and guaranteed issue on health insurance companies that sell to individuals as well as to groups. Their decisions, controversial at the time, have had a major impact on the health insurance marketplaces in those states.

### Early Warning

In 1993, when community rating and guaranteed issue were first imposed on the individual health insurance markets in New Jersey, New York, and Vermont, a study produced for the Council for Affordable Health Insurance (CAHI) warned the mandates would make the problems of high insurance premiums and lack of access to insurance worse, not better.

"Most of today's uninsured are young and do not have much money," the CAHI report said. "Community rating forces them to subsidize the cost of the middle-aged, who are at the peak of their earning power. Forcing the young to pay more will drive them out of the insurance market, raising costs for everyone."

Using a sophisticated health database called SimuCare, the authors showed how community rating would work in practice. Starting with a normal population of 100,000 people, the study predicted that eventually 31,500 people—mostly younger and lower-income people—would drop their insurance coverage because of higher prices. Approximately 10,000 older and less-healthy people would buy insurance. With fewer people to share the cost and with higher expected health costs, premiums would have to go up ... by about 25 percent, according to the SimuCare model. That increase would come on top of the rate increases caused by inflation, cost-shifting, increased utilization, and other trends.

The CAHI report did not address guaranteed issue. If it had, it would have found similar results. Guaranteed issue laws increase the average age of the insurance pool and attract sicker people to it. Insurance premiums have to go up to subsidize the newcomers because they tend to have (sometimes serious) medical conditions, just as community rating forces the young to subsidize the middle-aged and elderly.

"Community rating will not work to extend coverage" to the currently uninsured, the CAHI study concluded, "because, as predominantly young, low-income people, they have difficulty allocating scarce dollars to insurance premiums. Additionally, it is precisely this population that experiences the biggest premium increases from going from risk-based premium rates to community-rated premiums."

### Ten Years Later

Today, some 10 years later, it is possible to put CAHI's predictions to the test. What has happened to individual insurance markets in the eight states that adopted community rating and/or guaranteed issue beginning in 1992 and 1993? The data tell a grim story:

- Between 1992 and 2001, the share of the population in these eight states covered by individual health insurance plans fell to 18.8 percent below the average of the other 43 states and the District of Columbia.
- The eight states have seen a massive exodus of private insurance companies that had been selling individual health insurance policies. Some 45 insurers, for example, left Kentucky between 1994 and 1997.
- Premiums for individual insurance have soared. In Maine, for example, the monthly premium for a family policy for someone aged 25 ranges from $1,116 to $4,337.
- By contrast, premiums in states that did not adopt guaranteed issue and/or community rating have seen much smaller rate increases. For example, typical monthly insurance premiums for families in rural counties in Vermont are approximately five times as much as they are for families in rural counties in Illinois.

### An Eight-State Series

Starting with New Jersey in this issue, *Health Care News* will present a monthly series of case studies documenting how community rating and guaranteed issue have destabilized and sometimes destroyed the private individual insurance markets in states that adopted such legislation. Each case study will offer an overview of legislative activity since 1992 (or the year the legislation was adopted), data on uninsured rates and participation in the individual insurance marketplace, and premium costs for typical families.

The case studies will also provide comments from people in the states—individuals, small business owners, business and civic leaders, elected officials, and regulators—giving their own perspectives on what has happened during the past decade. We also will report on alternatives to community rating and guaranteed issue where they've been tried.

As this introduction suggests, the lesson from this series is already clear: Imposing community rating and guaranteed issue on the individual health insurance market causes premiums to rise, not fall, and makes it more difficult, not easier, for the uninsured to find affordable coverage.

*Joseph L. Bast is president of The Heartland Institute and publisher of* Health Care News. *His email address is* **jbast@heartland.org**.

**Guaranteed Issue**

Guaranteed issue (GI) laws forbid health insurance companies from denying coverage to anyone who applies for health insurance, including those individuals who apply for insurance after the onset of a chronic health condition or who have made lifestyle choices known to be unhealthy. Adopted to help end "job lock," GI has the unintended consequence of encouraging people to wait until they get sick before buying health insurance, which increases the number of uninsured and the premium costs for those who remain insured.

**Community Rating**

Pure community rating (CR) laws require health insurance companies to charge the same premium to everyone, regardless of age, sex, health history, lifestyle choices, and regional demographics. This one-size-fits-all rate results in charging young and healthy people higher premiums than their expected medical expenses would otherwise justify in order to subsidize rates for middle-aged, older, and less-healthy people.

Under "modified" CR, premium variations are allowed to compensate for certain risk characteristics such as age, sex, and family size, but not for others such as health status or lifestyle choices.

*— C.M.*

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PART 1 IN A SERIES

# The New Jersey Car

by Conrad F. Meier

Welcome to New Jersey, where people with individual health insurance routinely pay more than $12,000 a year for premiums, and can spend as much as $263,904.

Thanks to regulations passed in 1992, New Jersey has some of the highest insurance premiums in the entire country and an individual health insurance industry that is on life support. New Jersey legislators have passed many health insurance laws during the past decade, mostly to fix problems caused by the original 1992 reforms. But there is little evidence policymakers are willing to reexamine the flawed policies that have wrecked the state's health insurance industry and robbed its customers of their freedom to choose affordable and high-quality policies.

### Legislative History

In 1992, New Jersey Blue Cross and Blue Shield (NJBCBS) was the state's "insurer of last resort," meaning it was required to issue health coverage in the individual market to persons who did not qualify for group coverage or Medicare or Medicaid. Some 175,000 persons were insured in 1992 by NJBCBS under individual plans.

According to one estimate, NJBCBS lost $20 million on its individual insurance policies in 1992 but received subsidies to offset its losses, financed by a surcharge on hospital rates. In May 1992, a federal court ruled the surcharges violated the Employee Retirement Income Security Act of 1974 (ERISA), a federal law that preempts state intrusion into employer-based, self-funded health plans. Although that ruling was subsequently reversed, NJBCBS feared the loss of its subsidy and lobbied for legislative relief.

The result was the Individual Health Coverage Program, requiring insurance carriers doing business in New Jersey to either offer individual health insurance on a guaranteed issue basis or pay an assessment to carriers that did. Other elements of the legislation were:

- Guaranteed coverage and renewability for all eligible people regardless of their health status. A pre-existing condition exclusion may allow insurers to limit coverage during the first 12 months.
- Guaranteed renewal of policies, provided (1) the insured does not become eligible for coverage under a group plan; (2) premiums are paid in a timely fashion; and (3) no fraud is committed by the insured.
- Community rating of the premiums, with variation allowed only for family status (single, adult plus child, husband and wife, and family).
- Standardized insurance plans, referred to as Plans A, B, C, and D (indemnity options) and a single HMO plan. (See Figure 1 for coverage details.)

Since 1994, insurers have been required to make sure total claims are at least 75 percent of the total premium collected. Carriers not meeting the requirement must develop a refund plan that state regulators approve. According to the New Jersey Department of Banking and Insurance, insurers have paid refunds totaling $61.2 million since 1994.

### Skyrocketing Premiums

According to John A Kalosy, HIA, the New Jersey legislative chairman for the National Association of Health Underwriters, "community rating linked with standard state mandated plan designs was like mixing nitrogen and glycerin and expecting it not to blow up. It was like watching two teenage drivers playing a game of 'chicken.'"

Monthly premiums for family coverage under "Plan D" ($500 deductible, indemnity insurance) offered in New Jersey by Aetna rose from $769 in 1994 to $5,855 in 2003, a stunning 661 percent increase. Increases by NJBCBS, Metropolitan Life, and National Health Insurance were similar. (See Figure 2.)

The *annual* premium cost for a family Plan D policy from Aetna is an incredible $70,260. The cost of similar coverage from other carriers is only slightly less: $63,828 for NJBCBS, $56,820 for Metropolitan Life, and $54,552 for National Health Insurance.

The four carriers in Figure 2 were chosen because they have sold Plan D policies since 1994. They are neither the most expensive nor the least expensive insurers in New Jersey. Trustmark, for example, charges $17,550 a month for Plan D—$210,600 a year. Celtic charges an amazing $21,992 a month—$263,904 a year!

The *lowest* monthly premium for a family Plan D policy, as of December 2003, was $3,810 offered by Oxford. Figure 3 shows the lowest monthly premiums charged for each of the four indemnity plans and the HMO plan required under the Individual Health Coverage Program. The lowest rate in the table is $424/month ($5,088/year) for PPO coverage for a single individual (not family) with a $1,000 deductible.

"New Jersey state legislators are unable or unwilling to cut benefits out of the standard plans becasue of perceived political pressure," says Kalosy. "The average consumer is unable to afford the high cost of the individual health plans."

**"Average monthly premiums for family coverage under 'Plan D' ($500 deductible, indemnity insurance) offered in New Jersey by Aetna rose from $769 in 1994 to $5,855 in 2003, a stunning 661 percent increase."**

### Declining Coverage

The second impact of the 1992 reforms was a dramatic decline in the number of people who have individual health insurance. High prices have driven the number down from historic levels in New Jersey as well as from levels in states without community rating and guaranteed issue.

Exactly how many people buy individual health insurance in New Jersey is controversial, but data from three sources all show a rapid decline. (See Figure 4.)

- According to U.S. Census Bureau data, the number of persons in New Jersey with individual health insurance fell from 898,000 in 1992 to 552,000 in 2001.
- According to the Employee Benefits Research Institute, which excludes persons age 65 and older from its estimates, the number of people with individual coverage fell from 500,000 in 1992 to 300,000 in 2001.
- Finally, the New Jersey Individual Health Coverage Program estimates the number of individual insurance policies fell from 156,565 in 1993 to 78,298 in 2003.

### Fleeing Carriers

The third impact of the 1992 reforms has been a decrease in the number of insurance carriers willing to sell individual insurance in New Jersey.

Until a few years ago, proponents of the 1992 reforms maintained the program worked. In mid-1999, for example, Katherine Swartz (Harvard School of Public Health) and Deborah Garnick (Brandies University) referred to the program as an "unprecedented achievement." To justify their praise, they cited the fact that in 1995 28 carriers were serving the

**Figure 1: Coverage Under Standard Plans Required by the Individual Health Coverage Program**

| Plan | Deductibles/Co-pay | Coinsurance | Hospital Confinement Deductible |
|---|---|---|---|
| A | $1,000, $2,500, $5,000, $10,000 | 50/50 to $10,000 | N/A |
| B | $1,000, $2,500 | 60/40 to $10,000 | $200/day |
| C | $1,000, $2,500, MSA | 70/30 to $10,000 | N/A |
| D | $500, $1,000, MSA | 80/20 to $10,000 | N/A |
| HMO | $10, $15, $20, $30 | N/A | Yes |

**Figure 2: Monthly Premium for Family Coverage Under Plan D**

Source: http://www.state.nj.us/dobi/ihcrates.htm

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# r Wreck

New Jersey individual market with guaranteed issue products.

By December 2003, however, only 15 carriers served the market. Even this lower number overstates the amount of competition in the market. Counting only carriers with distinct corporate parents reduces the number of firms to 11. And the very high premiums charged by some companies suggest they are filing rates but not selling polices.

Why companies left is not difficult to understand. Guaranteed issue means people with chronic illnesses cannot be turned down for individual health insurance coverage, even though by traditional underwriting standards they are uninsurable. Community rating means carriers are forced to set their premiums sufficiently high to cover these "worst case" customers, making their policies unaffordable to virtually anyone else. The result is a "death spiral" of ever-rising premiums and "adverse selection," where only those with poor health and high medical expenses choose to buy individual insurance.

Making an already-bad situation worse, in 1996 insurance companies were assessed $43.5 million to offset the losses of NJBCBS. By August of that year, NJBCBS had been reimbursed $81.5 million for its losses in the individual market. If anyone benefitted from the 1992 legislation, it was NJBCBS. Most of its competitors have been driven out of business or out of the state.

### Trying to Repair the Damage

Additional new regulations soon followed, prompted largely by market responses to the 1992 and 1994 regulations. In 1998, following public complaints about the quality of managed care, a law was enacted to regulate HMO conduct. In 1999, following the high-profile bankruptcy of Garden State, an indemnity insurer, regulators were given greater authority over insurer solvency. In 2000, legislation was passed to bail out two bankrupt HMOs.

In 2001, more legislation was adopted concerning HMO conduct, this time making external panel recommendations mandatory and giving private consumer groups ombudsmen-like authority over HMOs. Legislation adopted in 2002 created a "Basic and Essential Coverage" plan stripped of mandates and the community rating standard. For example, it provides for only 90 days of hospital room and board with a $500 per-hospital stay deductible. However, rates for those policies will be regulated. The Individual Health Coverage Program Board is only now engaged in rulemaking with respect to this plan and no rates are available.

In November 2003, New Jersey Governor James McGreevey signed legislation creating a Mandated Health Benefits Advisory Commission to study the "social, financial, and medical impact of proposed mandated health benefits." The 15-member commission will review any proposed legislation that would require health insurance carriers to provide specific health benefits.

### Conclusion

It has been more than 10 years since New Jersey legislated sweeping changes to its individual health insurance code. The combination of guaranteed issue and community rating has nearly destroyed the market for health insurance for individuals.

Most of the new laws adopted since 1994 have failed to address the real sources of the damage caused by the state's sweeping insurance regulations adopted in 1992. Instead, these subsequent laws battle the unintended consequences of bad policies, such as bankruptcies, rising premiums, and unacceptable and financially unstable HMOs.

**"Thanks to regulations passed in 1992, New Jersey has some of the highest insurance premiums in the entire country and an individual health insurance industry that is on life support."**

Lawrence Koller, an independent insurance broker in Northern New Jersey and member of the National Association of Health Underwriters, says "a major problem is that no politician wants to face these issues. No one wants to take away benefits. In fact, if a politician is sitting in his/her office and a constituent comes in complaining their insurance doesn't cover something, the politician is more likely to try to help the constituent by offering a new mandate that the health plan has to cover. The impact on rates and potential future 'uninsured' doesn't seem to be given as much weight."

Koller goes on to say, "The media don't help either. The typical news report doesn't distinguish between large group, small group, and individual insurance markets. The public and politicians lump all insurance companies together as the bad guys—the ones with the deep pockets."

Enactment in 2002 of the "Basic and Essential Coverage" plans with fairly broad rate bands is a small but favorable step back from the abyss. The legislation recognizes the need to allow carriers to offer individual health insurance plans that are attractive to the young and healthy. It seeks to accomplish this, though, by allowing insurers to offer deliberately crippled insurance products that the chronically ill won't want to buy. New Jerseyans deserve affordable individual health insurance policies without being forced to settle for policies that limit coverage to 90 days of hospital room and board and require a $500 per-hospital stay deductible.

There seems to be little interest among New Jersey legislators in abandoning the community rating and guaranteed issue mandates that have caused the state's insurers and their customers so much suffering. Until that attitude changes, New Jersey will remain the "poster child" for how to destroy a health insurance market.

*Next month: Vermont*

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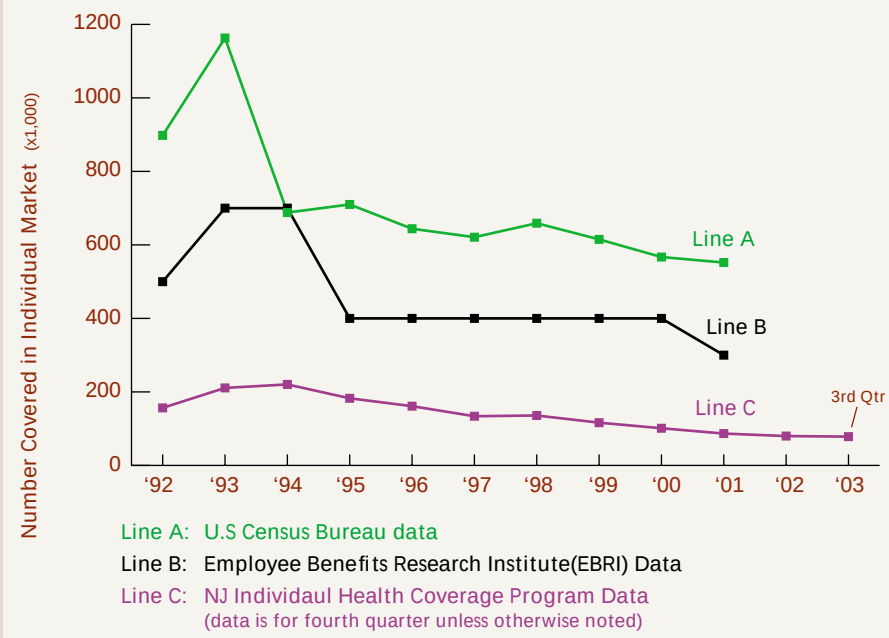
**Figure 3: Lowest Monthly Premiums for Individual Health Insurance in New Jersey, December 2003**

| Plan | Status | Deductible/ Lowest Copay | Monthly Rate | Carrier |
|---|---|---|---|---|
| A | Single | $1,000 | $502 | Oxford |
| A | Adult + Child | $1,000 | $1,005 | Oxford |
| A | H&W | $1,000 | $995 | Oxford |
| A | Family | $1,000 | $1,433 | Oxford |
| B | Single | $1,000 | $734 | NJBCBS |
| B | Adult + Child | $1,000 | $1,262 | Aetna |
| B | H&W | $1,000 | $1,470 | Aetna |
| B | Family | $1,000 | $1,855 | NJBCBS |
| C | Single | $1,000 | $424 | Oxford PPO |
| C | Adult + Child | $1,000 | $784 | Oxford PPO |
| C | Adult + Child | $1,000 | $1,669 | Aetna |
| C | Family | $1,000 | $1,208 | Oxford PPO |
| D | Single | $500 | $1,337 | Oxford |
| D | Adult + Child | $500 | $2,473 | Oxford |
| D | H&W | $500 | $2,674 | Oxford |
| D | Family | $500 | $3,810 | Oxford |
| HMO | Single | $15 | $468 | NJBCBS |
| HMO | Adult + Child | $15 | $718 | NJBCBS |
| HMO | H&W | $15 | $1,001 | NJBCBS |
| HMO | Family | $15 | $1,417 | NJBCBS |

Source: http://www.state.nj.us/dobi/ihcrates.htm

**Figure 4: Number of Persons Buying Individual Health Insurance Plans in New Jersey**




Source: http://www.state.nj.us/dobi/ihcrates.htm

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Greg Scandlen

# HSAs and Some Devilish Details

Some readers will find the discussion below tedious, and I apologize for that. We'll get back to fun stuff next month ... but how well Health Savings Accounts (HSAs) work will depend on how the IRS regulations shake out. I'll give you my best take on these issues, but this is all gray-area stuff. Keep in mind that the only opinion that really counts is the IRS's.

**Combining HRAs and HSAs**

One of the implications of the new HSA reforms is combining a Health Reimbursement Arrangement (HRA) with an HSA. Some people I respect highly have conjectured it would not be allowed because the HRA duplicates the benefits of the high-deductible health plan (HDHP), and an HRA would be allowed only if it does not duplicate those benefits. That is, the HRA might be allowed for peripheral benefits like vision or dental, but not for the core benefits the HDHP would otherwise cover.

That is not the way I see it. I believe the law says the minimum deductibles of $1,000/$2,000 are sacrosanct. There may be no coverage below those amounts, other than the HSA. But once you've broken through that threshold, benefit construction is wide open.

What I am reading says: "[To be eligible for an HSA] such individual is not, while covered under a high deductible health plan, covered under any health plan which is not a high deductible health plan, and which provides coverage for any benefit which is covered under the high deductible health plan."

This says (as far as I can see) that an individual is disqualified from an HSA if he has coverage that duplicates the benefits of the high-deductible plan AND which is not a high-deductible plan. Both conditions must be present. Please correct me if I'm missing something, but I see no reason that an account-holder could not be covered by two plans if they are both high-deductible health plans.

So, an employer-funded HRA could be used to fund another deductible on top of the HSA-funded deductible, or the HRA could be used to cover coinsurance on top of the HDHP deductible. The HRA is, after all, just part of the HDHP. That is especially true for self-funded employers (it is all Section 105 money), but should be true for insured situations as well.

**Converting HRA Funds**

Many employers have asked about HRA conversions. If there is an HRA in place and the company switches to an HSA, can employees continue to access the HRA funds—in effect, "spend-down" the HRA money? Again, it would seem this should be allowable, provided the HRA money doesn't fill the minimum deductible. Or, if the HRA plan document allows it, an employer could reclaim the HRA fund, and use that obligation as a source of HSA funding.

**"We cannot continue to treat adult Americans like hapless children who are unable to make decisions and value judgments in health care. People are able to learn from experience, and beginning in 2004, we have a tool that allows that to happen."**

**Carving out Rx Benefits**

Some employers have told me they would like to carve out prescription drug benefits from the HSA/HDHP package, and continue to offer these on a triple-tier copayment basis, or fund it with an HRA. I cannot see any way the law would allow this. It is quite specific on what are "permitted coverages" below the deductible, and Rx isn't one of them.

**Non-Discrimination**

Another issue that has been raised is the application of non-discrimination rules. I hadn't heard of this before, but I've been told if, in the course of setting up a Flexible Spending Account (FSA) program, it turns out only "highly compensated employees" choose to participate, the whole program can be disqualified after-the-fact.

The fear is that applying the same standard to an HSA program could be very messy, involving a return of worker's contributions and re-enrollment in a different health plan even after the plan year has begun. There seems to be some relaxation of the non-discrimination rules for HSA programs, but it isn't clear how far it goes.

**Independent Substantiation**

Much-discussed has been the question of independent "substantiation" of HSA withdrawals. FSAs and HRAs require that a withdrawal be certified as a qualified medical expense under Section 213(d). There are severe penalties on the employer if these moneys are used for non-qualified expenses. In the case of an HRA, it may mean losing the tax advantage of the entire benefits program. Non-medical withdrawals are absolutely forbidden.

That is not the case with HSAs. People are perfectly free to use HSA money for non-medical purposes, as they have been with MSAs. The only penalty is that the account-holder (not the employer) pays taxes on the funds, plus a 10 percent penalty.

The HSA trustee will issue a statement to the IRS about deposits and withdrawals, and the account holder is required to verify that the withdrawals were for qualified expenses.

This is also how the medical expense deduction works. People are free to claim anything as a medical expense on their tax returns. The claims are not independently verified. But if the taxpayer is audited, there are severe penalties for fraudulent claims. It seems to work pretty well in keeping people honest.

**Adjudicating HSA Withdrawals**

Some employers would like to go beyond "substantiation" and have HSA withdrawals treated like any other insurance claim, i.e., submitted for adjudication and re-pricing so that the employee will get the "benefit" of network discounts and the employer knows whether the service is eligible for meeting the deductible.

This issue indicates many employers still don't "get it." The HSA money belongs to the worker, not the employer. The whole point is to get workers involved in the cost of the services they consume and begin to demand transparent pricing from the doctors and hospitals they deal with. So-called "network discounts" are fictitious. They are discounts from a "charge" that is never actually paid by anyone. HSAs will place more of the health care system on a cash basis, which is far more efficient than the existing third-party payment system. And it will begin to restore true prices that reflect value.

In the short run, some workers may very well spend their HSA money frivolously and be over-charged for services. But that is the precise learning process our entire system needs to go through to change the fundamental economic dynamics in health care. We cannot continue to treat adult Americans like hapless children who are unable to make decisions and value judgments in health care. People are able to learn from experience, and beginning in 2004, we have a tool that allows that to happen.

I welcome your comments on whatever the IRS has to say about these issues. Send your thoughts to me at **GMScan@aol.com**.

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# Rx Discount Cards Could Pave Way for Future Reform

**by Grace-Marie Turner**

The Medicare Prescription Drug Improvement and Modernization Act of 2003 creates a new Medicare prescription drug discount card and transitional assistance program.

The legislation requires the Department of Health and Human Services (HHS) to implement a new program of Medicare-approved prescription drug discount cards. Seniors who participate in the voluntary program will receive discounts on their prescription drug purchases negotiated by private card sponsors. The program also provides a cash subsidy for lower-income seniors.

### Discount Cards

Congress specified the discount card program would take effect no later than six months from the date of enactment of the legislation. On December 10, 2003—two days after the legislation was signed by President George W. Bush—HHS published an "interim final rule" establishing the Medicare Prescription Drug Discount Card Program, providing a 30-day comment period. The Medicare-endorsed drug discount cards are expected to become available in the spring of 2004.

The legislation specifies application processes for drug card programs, including a standard enrollment form, and it specifies the sponsor can collect annual enrollment fees of up to $30. States may opt to pay the enrollment fees for their citizens to encourage participation in the program.

HHS estimates those enrolled in the drug discount programs will receive savings of 10 to 25 percent on their prescription drug purchases. Participants may join only one Medicare-endorsed discount card program at a time. Participants will be allowed to change from one card sponsor to another at the beginning of 2005.

Card sponsors can be pharmaceutical benefit management companies, wholesale or retail pharmacies, insurers, Medicare+Choice health plans, or any combination of the above.

The participating drug card sponsors must have participation by bricks-and-mortar pharmacies in the regions where they are offering the cards in addition to possible mail-order dispensing. Seniors must have a choice of at least two discount card programs, offered by different sponsors.

The legislation stipulates that: "The prices negotiated from drug manufacturers for covered discount cards under an endorsed discount card program shall not be taken into account for the purposes of establishing the best price for government programs."

### Low-Income Subsidies

A key part of the program is a subsidy of up to $600 a year for eligible lower-income beneficiaries. Individuals whose income is less than 135 percent of poverty—$12,124 each year for individuals or $16,363 for married couples, according to HHS—may qualify for the cash subsidy. Medicare beneficiaries who are also eligible to receive assistance for prescription drugs through Medicaid would not be eligible for either the drug discount cards or the cash subsidy.

For "transitional assistance eligible individuals," the federal government will pay any annual enrollment fee for the drug discount cards and also will provide a subsidy on the drug discount card of up to $600 in 2004 and 2005. The legislation describes two categories of assistance: Persons with incomes below 100 percent of poverty would be responsible for copayments of 5 percent of incurred drug costs up to $600, and those with incomes of 100 to 135 percent of poverty would have 10 percent copayments. Any balance left over from the $600 subsidy at the end of 2004 may be added to the amount available in 2005.

**"The drug discount card program, and particularly the $600 subsidy for lower-income seniors, provide an excellent model for future programs."**

The legislation stipulates the temporary discount card program and the $600 subsidies are to expire on December 31, 2005, at which time seniors are expected to enroll in one of the new subsidized prescription drug plans that begin in 2006 or in a Medicare Advantage plan.

### Implications for Future Policy

The drug discount card program, and particularly the $600 subsidy for lower-income seniors, provide an excellent model for future programs. Drug prices are privately negotiated by the card sponsors, not set by government fiat. Also, the $600 subsidy for lower-income seniors is a defined contribution that gives government certainty over its program costs. Seniors get control over drug purchase decisions and an incentive to make the dollars go as far as possible.

**Several pharmaceutical companies currently offer prescription drug benefit cards enabling seniors to receive discounts when purchasing their prescriptions.**

The rollover provision for the cash assistance provides particularly good incentives: Unlike a use-it-or-lose-it benefit structure, the rollover gives seniors the opportunity to conserve resources for future needs. While the program is temporary, it provides a good marker for future programs. Seniors should be given the opportunity to continue to participate in this program if they prefer it to the new free-standing Medicare drug benefit program due to start in 2006.

Also beginning in 2006, the new Medicare Advantage (MA) health plans can incorporate the prescription drug coverage created by the legislation into their benefit structure. Because the legislation gives the new MA plans leeway in how they structure the drug benefit, they may consider building a benefit on the model of the temporary drug discount and assistance program.

They could provide an up-front cash subsidy that seniors could use for their initial prescription drug purchases. The plan could then require cost-sharing for drugs in the next tier of expenditures and umbrella insurance coverage for large prescription drug expenses, with an even lower copayment required.

This model would provide access to funds for routine drug purchases at competitively negotiated prices while providing insurance protection against large drug expenses. Importantly, it would give seniors an incentive to be partners in managing their prescription drug expenditures.

The MA plans would be the agents providing seniors competitively negotiated prices. Unspent funds in the cash account could be rolled over to the next year. MA plans likely would find using the temporary drug program an attractive model for structuring their drug benefit for plan participants.

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## Medicare's Long Rx History

**May 1967:** Task force studies adding drug benefit to Medicare, but no legislation evolves.

**August 1997:** President Bill Clinton signs the 1997 Balanced Budget Act (PL 105-33), which among other things creates the Medicare+Choice program to encourage beneficiaries to join private managed care and other health plans offering prescription drug benefits.

**January 1998:** Senator John Breaux (D-Louisiana) and Representative Bill Thomas (R-California) co-chair the National Bipartisan Commission on the Future of Medicare. A majority of the panelists endorse the concept of "premium support" and more competition between Medicare and private companies. Fourteen months later the commissions disbands with no agreement and no suggestions for legislation.

**February 2001:** Breaux and Senator Bill Frist (R-Tennessee) introduce bills allowing private insurance companies to compete for Medicare enrollees by offering prescription drug coverage. Both measures die in committee.

**March 2001:** The Congressional Budget Office estimates adding a prescription drug benefit to the Medicare program might cost more than $1 trillion over the next decade.

**April 2001:** The Senate adopts, 51-50, an amendment by Senator Charles E. Grassley (R-Iowa) to a budget resolution (H Con Res 83). The amendment would reserve $300 billion over 10 years to fund a prescription drug benefit.

**July 2001:** President George W. Bush announces a plan for a privately administered prescription drug discount card. Two months later, a federal judge overturns the program because Congress did not authorize it.

**June 28, 2002:** The House passes a Medicare reform bill costing $350 billion over 10 years. The bill would allow beneficiaries to buy private insurance policies for drug coverage. The bill dies in the Senate without consideration.

**July 2002:** The Senate votes on four different prescription drug plans offered as amendments to legislation making it more difficult for drug companies to block approval of less-expensive generic drugs. All four plans fail to muster the 60 votes needed for passage.

### Rx Benefit Arrives

**January 28, 2003:** In his State of the Union address, Bush announces his budget proposal would provide $400 billion over 10 years to modernize Medicare and create a prescription drug benefit.

**June 27, 2003:** The House passes its version of the drug benefit by a one-vote margin, 216-215. The Senate passes its version 76-21.

**July 7, 2003:** The Senate names conferees to a joint Senate- House committee that will hammer out differences between the two bills.

**July 14, 2003:** The House names its conferees.

**November 15, 2003:** Republican leaders and some of the conferees reach a conference agreement.

**November 22, 2003:** The House adopts the conference report, 220-215.

**November 25, 2003:** The Senate adopts the conference report, 54-44, clearing the bill for delivery to Bush.

**December 8, 2003:** Bush signs the Medicare Prescription Drug Improvement and Modernization Act of 2003. A temporary drug discount plan will launch in spring 2004. The more formal Medicare prescription drug plan is scheduled to begin in 2006.

*— C.M.*

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# Responding to Critics of HSAs

**by John C. Goodman**

**Myth:** *Health Savings Accounts (HSAs) will not be popular.*
**Response:** HSAs will revolutionize the U.S. health care and health insurance industries. Authoritative sources, like the Bureau of National Affairs and *Health Affairs* journal, predict consumer-driven plans like HSAs will dominate the health insurance market in less than five years. In a recent poll, two-thirds of the members of the National Association of Business Economists said consumer-driven plans were the future of health insurance.

**Myth:** *HSAs have no tangible benefits.*
**Response:** Expanding HSAs will dramatically improve health care by reducing the need for managed care rationing, allowing workers to save for health needs in retirement; containing medical inflation by giving consumers an incentive to forgo unneeded care; and eliminating waste and bureaucracy by giving patients a stake in the savings.

**Myth:** *HSAs are not politically viable.*
**Response:** HSAs appeal to liberals because they offer an alternative to HMO rationing; conservatives like them because they are an alternative to government rationing.

**Myth:** *HSAs will be expensive to administer.*
**Response:** Administrative costs should be lower for HSAs than for managed care; in fact, administering HSAs should be no more difficult than using a debit or credit card.

**Myth:** *Why would HSAs be successful when fewer than 1.5 million workers are now enrolled in consumer-driven plans, like Archer MSAs?*
**Response:** HSAs replace Archer MSAs and do not suffer from the "use it or lose it" provisions restricting Archer MSAs. Health care contributions and investment gains rolled over from year to year have the potential to accumulate huge balances, putting consumers in a better position to pay for their own health care as they grow old and costs typically peak. In addition, the new law gives HSAs the same tax advantages now granted only to health insurance premiums.

**Myth:** *HSAs won't help solve the problem of uninsured Americans.*
**Response:** HSAs and other consumer-driven health insurance plans reduce the number of uninsured by making coverage more affordable. According to the IRS, for example, 73 percent of Americans with MSAs were previously uninsured.

**Myth:** *HSAs are a tax shelter for high-income Americans.*
**Response:** Beginning January 1, 2004, some 250 million non-elderly Americans are eligible to enroll in HSAs. Because premiums will be lower and any unused money can be rolled over to succeeding years, HSAs are more attractive to low-income than high-income workers.

**Myth:** *People will skimp on needed medical care to save money in HSAs.*
**Response:** The evidence shows that's not the case. In South Africa, for example, where MSAs have captured half of the health insurance market, an NCPA study found no evidence that MSA account holders skimp on needed care. That's consistent with a major finding of the RAND Health Insurance Experiment.

**Myth:** *HSAs won't control costs.*
**Response:** Health accounts encourage patients to shop and control costs. In South Africa, MSA enrollees spend 47 percent less on average for non-chronic prescription drugs than those with traditional insurance.

**Myth:** *HSAs will encourage employers to cut benefits.*
**Response:** Employers don't need a law to cut benefits. Employers who cut benefits risk losing workers, with or without HSAs.

**Myth:** *HSAs fragment the insurance risk pool.*
**Response:** HSAs do not fragment the "insurance risk pool" because there is no such thing: There are tens of thousands of risk pools in the U.S. In addition, HSAs won't fragment the risk pool because everyone stands to gain.

**Myth:** *HSAs will adversely affect people with chronic illnesses.*
**Response:** Because the maximum out-of-pocket cost (cost-sharing) is limited to $5,000 per individual, people with chronic illnesses may actually be better off under HSAs.

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# Seniors

Continued from page 1

Medicare reform measure were finalized and known. The December CNN/USA Today/Gallup poll showed much more subdued support for the specific bill than there had been for the general proposal to cover prescription drugs under Medicare.

### Worry over Complexities

Senior citizens are clearly interested in the new legislation and have been following news accounts of its passage. The December poll showed 73 percent of respondents 65 and older have read or heard at least a moderate amount about the new bill—much higher than the percentage of those under age 65 who have been paying attention.

Additionally, when asked about AARP's position on the bill, 61 percent of seniors recalled that AARP supported the plan, while only 10 percent thought AARP had opposed it.

These findings suggest the senior population is well-informed on the reform measure. The drop in support for the legislation, compared to the greater support for the general notion of prescription drug benefits covered by Medicare, likely reflects seniors' concerns about some of the law's specific provisions.

It is also evident realistic opinions about the real impact of the law may not be available for years. Most of the provisions of the legislation won't take effect until 2006, and it may take that long for those affected to grasp what Medicare reform really means to them.

The almost-700-page bill is exceedingly complex, involving a complicated mix of deductibles, exclusions, and amounts above and below which drug costs won't be reimbursed. The new law also makes numerous changes to Medicare, well beyond the new prescription drug benefit.

Previous polling showed seniors are less likely than those under 65 to feel Medicare needs a major overhaul, and more likely to believe changes made to the program may do as much to harm the system as good.

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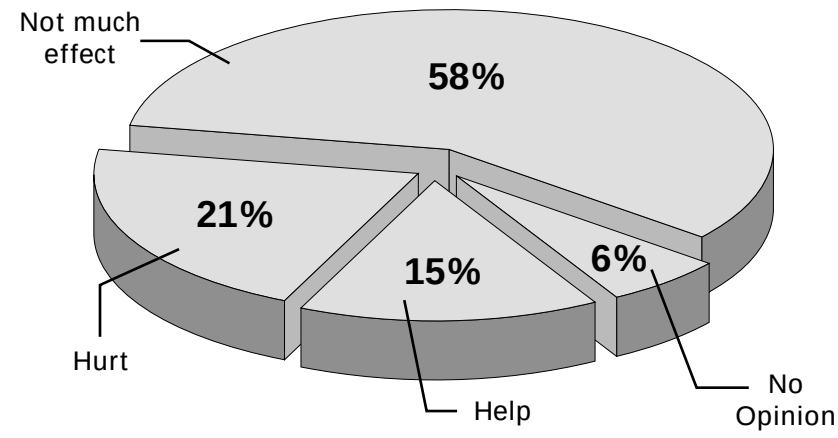
## INTERNET INFO

The CNN/USA Today/Gallup poll was conducted December 5-7, 2003. Telephone interviews were conducted with 1,083 adults, aged 18 and older, including more than 173 randomly selected Americans age 65 and older and an additional 79 senior citizens who had previously participated in national Gallup polls in 2003 and agreed to be re-contacted by Gallup for future polls. Complete details are available online at **http://gallup.com/poll/releases/pr031210.asp**.

**How Much Help: Adults 65 and Over**




Source: CNN/USA Today/Gallup December 2003

**Concern About Consequences of New Medicare Legislation**
**65 and Older Only**

| | Very concerned | Somewhat concerned | Not too/ Not at all concerned |
|---|---|---|---|
| Will benefit prescription drug companies too much | 58% | 20% | 15% |
| Will not go far enough to help seniors pay for their prescriptions | 56% | 29% | 10% |
| Will be too complicated for Medicare recipients to understand | 49% | 35% | 15% |
| Will force some Medicare recipients into HMOs | 48% | 25% | 21% |
| Will cost the government too much in the long run | 30% | 33% | 33% |

Source: CNN/USA Today/Gallup December 2003

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# "Best Practices" Provoke Controversy, Opposition

**by Twila Brase, R.N.**

The notion of "best practices" is an emerging concept in health care policy and practice. Exactly what it means and how it will affect patient care are open to debate.

### Minnesota Considers "Best Practices" Language

Minnesota House Republicans introduced "best practices" language into a health care cost containment bill (HF 1681) as a shield against medical malpractice lawsuits. The bill states, "In an action against a provider for malpractice, error, mistake, or failure to cure, whether based in contract or tort, adherence to a best practice guideline approved by the Board of Medical Practices is an absolute defense against an allegation that the provider did not comply with accepted standards of practice in the community."

If enacted, the legislation will change medical practice in Minnesota in three significant ways.

- First, it could be inferred that any practice not approved by the Board is malpractice, and therefore ripe for litigation.
- Second, health care decision-making would be centralized in a bureaucratic quasi-government institution with committee processes essentially dictating availability of care.
- Third, medical practice would be infused with politics as Board members became the target of lobbying by insurers, employers, patient advocates, professional associations, pharmaceutical companies, and medical device manufactures.

The Minnesota Board of Medical Practice currently has a limited purpose. According to the Board's 2002 Biennial Report, its mission is "to protect the public by extending the privilege to practice to qualified applicants, and investigating complaints relating to the competency or behavior of individual licensees or registrants." Republicans propose to substantially expand that mission.

Although proposed as a remedy for unnecessary medical malpractice litigation, there is little evidence to assure patients that following "best practices" will improve their medical care. The possibility of severe penalties for doctors straying outside the "best practices" box will more likely lead to rationing of care.

### National Guidelines?

"Best practices" has gained a national audience as well, most recently through an Institute of Medicine (IOM) publication, "Patient Safety: Achieving a New Standard for Care." The report supports the establishment of a National Health Information Infrastructure (NHII) to facilitate sharing of patient data and dissemination of best practice guidelines to direct physician treatment decisions.

As envisioned, the NHII would facilitate information exchange on three levels: (1) personal health, to provide information to individuals about wellness and health care decision-making; (2) health care providers, to provide 24/7 access to detailed patient data and clinical decision support systems; and (3) public health, to facilitate state and federal public health surveillance activities.

In IOM's vision of a new health care system, best practices and clinical decision support systems would be used together to direct physician practice. Computerized decision support systems take many forms, according to the report's authors: reminders, alerts, embedded controls, decision assistance, and risk prediction using the "most up-to-date evidence from the research literature and practice-based resources."

Research and evidence-gathering are funded by the Agency for Healthcare Research and Quality (AHRQ). Thirteen evidence-based practice centers (EPCs) around the country are working to churn out practice guidelines derived from analysis of studies on "clinical, social science, behavioral, economic, and other health care and delivery issues."

These computerized "evidence-based" guidelines could be sent directly into the exam room, where physicians can be prodded by computers to perform in sync with the guidelines. As the report notes, "Putting evidence-based guidelines into a computer-readable format that can be used with decision support systems during clinical encounters is the objective of the informatics community."

Once set in motion, the computerized systems would not only encourage practitioner cooperation, but also monitor practitioner compliance. Throughout the report, the authors note several possible ways the national health information infrastructure could be used to influence medical decision-making:

- linking patient outcomes with those responsible for those outcomes;
- measuring physician performance;
- monitoring compliance with best practices;
- ranking doctors and hospitals;
- providing financial rewards to practitioners based on performance ranking;
- submitting data to a national patient safety database; and
- permitting state and federal government health surveillance.

### A Difficult Task

Determining what constitutes a "best practice" is a difficult task.

The IOM authors acknowledge "there are gaps and inconsistencies in the medical literature supporting one practice versus another, as well as biases based on the perspective of the authors, who may be specialists, general practitioners, payers, marketers, or public health officials." Consequently, it is likely biases will be found among those who analyze studies and determine what "evidence" will be used to create the guidelines that appear on a doctor's computer screen.

Moreover, insufficient clinical research exists to support evidence-based medical policy and coverage decisions, according to a recent article in the *Journal of the American Medical Association*. In an interview published by Medscape Medical News, Nancy S. Sung, lead author of the JAMA article, makes four important points that in themselves show the difficulty of defining "evidence" and avoiding bias:

**1)** Comparative data on the effectiveness of old versus new technologies are not available.

**2)** Significant holes exist in the body of evidence on which clinicians and patients base treatment decisions.

**3)** Employers and health insurers find clinical research has not met their needs to support evidence-based decisions.

**4)** Purchasers and payers of health care have worked with the Clinical Research Roundtable to develop a prioritized list of research questions they need answered.

There is also reason to worry that "micromanagement" through a computer terminal may reduce health care access. Managed care has already led to early retirement of physicians and fewer nurses. Applications to medical school continue to slide. Further interference by health system "executives" or aggressive penalties for non-compliance will only exacerbate this workforce problem.

The IOM also acknowledges in its report what it calls "the cycle of fear." Authors note that use of performance data to rank, rate, or penalize a practitioner or institution may lead to defensiveness, gaming of the data system, or systematic manipulation of the data.

"Things we were forced to do back when I was in training would be considered malpractice today," noted Dr. Jane Orient, executive director of the Association of American Physicians and Surgeons. "Establishing a rigid definition of 'best practices' would have a chilling effect on doctors thinking for themselves, making improvements, and correcting errors in the accepted 'best practice' standard. There is no better way to stifle innovation than to increase the legal risk for not following the cookbook."

And finally, implementation of best practices may lead to a myopic focus on certain conditions with little attention to the other pressing needs of patients. In 2002 the IOM recommended 20 priority areas for evidence collection, practice guideline creation, and performance measurement development. Myriad conditions, and myriad iterations of conditions experienced by patients, are not on the list.

In theory, "best practices" sounds like a great idea. However, the standardization of health care and centralization of decision-making proposed in publications and legislation may not be as well-received by patients or practitioners. If a physician "fear factor" emerges alongside implementation of best practices, as the IOM cautioned, patients with complex requirements and unusual medical situations may find their doctors treating to a performance score rather than the needs of their patients.

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# TennCare

Continued from page 1

cluded McKinsey & Company, "and its cost growth in that year will represent 91 percent of new state tax appropriations."

"This has been a sobering day for me," said Tennessee Governor Phil Bredesen upon receiving the consultants' report. "The news is not good."

Bredesen had asked BlueCross BlueShield of Tennessee, Hospital Corporation of America, the Tennessee Farm Bureau Federation, 22 hospitals within the Tennessee Hospital Association, and Vanderbilt University to fund a study of TennCare. The group engaged McKinsey & Company to conduct the evaluation.

**Ambitious Program**

Launched in 1994, TennCare represents, the consultants write, "an historic effort to implement managed care for Tennessee's entire Medicaid population and expand insurance coverage to the state's uninsured and uninsurable residents." The program's budget has increased dramatically over the past decade and currently rests at $6.9 billion, of which the state pays $2.1 billion. The federal government picks up the remaining cost.

McKinsey & Company project the program's costs will reach between $11.8 and $12.6 billion by 2008. Program design features, program execution, and the overall health care environment are cited by the consultants as contributing factors to the program's growth. For example,

- TennCare's benefits have few limits. "It's really one of the only programs that has, almost across the board, no limits on scope and duration of coverage," said Vivian Riefberg, a partner in McKinsey & Company's Washington DC office. While most state programs limit the number of drug prescriptions an enrollee can fill per month, limit the number of hospital days the program will pay for, or require substantial co-pays, TennCare services are provided "as medically necessary," with no ceilings. TennCare requires co-pays only from its non-Medicaid beneficiaries. McKinsey & Company estimates increased prescription drug costs alone will account for 56 percent of TennCare's growth between 2004 and 2008.
- TennCare's design provides for inadequate cost control measures. For most services—including inpatient, outpatient, and home health care—the state works through managed care organizations (MCOs) rather than provide the services directly. According to McKinsey & Company, the cost controls implemented by the MCOs have been "inadequate." According to the report, "a series of high-profile MCO bankruptcies ... left providers absorbing financial losses for millions of dollars in unpaid claims." In July 2002, the state assumed the financial risk for all TennCare enrollees, and the MCOs now operate as administrators only.

**Ticking Bomb**

"The TennCare bomb has been ticking away for years, keeping no secrets about its volatility," editorialized the *Memphis Commercial Appeal* in December. *Health Care News* has covered the TennCare story for years, documenting several reasons for the program's failure:

> **"It's really one of the only programs that has, almost across the board, no limits on scope and duration of coverage."**
>
> VIVIAN RIEFBERG
> MCKINSEY & COMPANY

- It is far too ambitious, enrolling too many people. "TennCare insures 1.3 million residents—a higher percentage of a state population on a Medicaid expansion program than anywhere else in the country," wrote the McKinsey & Company consultants. Currently, 24 percent of the state's population is enrolled in the TennCare program. Nearby states, such as Alabama, Kentucky, Mississippi, and Missouri, enroll roughly one-third to one-half as many people in their Medicaid programs.
- TennCare enrolls a higher percentage of adults than children. In most other states, children represent more than half of the Medicaid beneficiary population. On average, adult Medicaid beneficiaries require more care than do children.
- TennCare enrolls all high-risk and medically uninsurable residents, as the state abandoned its stand-alone high-risk insurance pool. While middle- and upper-income TennCare enrollees with pre-existing conditions do pay monthly premiums, those premiums are not risk-based and never generate the revenue needed to cover actual medical costs.
- TennCare provides generous benefits, better in some respects than the plans offered by some private-sector employers. Although many employers, for example, do not offer prescription drug coverage, 22 percent of TennCare's budget pays for the drug benefit.
- TennCare's generosity acts as a magnet, drawing in an uninsured population from surrounding states. And the relative ease with which sick people can qualify for TennCare—one need only document having been turned down for private insurance—the system encourages people to wait until they need medical care before obtaining coverage. Many healthy Tennesseans have dropped private insurance knowing they will qualify for TennCare after they get sick.

Other factors beyond the state's control have contributed to TennCare's woes. Although health care spending moderated in the mid-1990s, most observers predict escalating health care cost increases in the future, for both public- and private-sector health care programs, for several reasons:

- Advanced medical technologies are driving hospital spending up as physicians are now able to do more than they used to.
- New federal and state benefit mandates require Medicaid to cover products and services otherwise not provided.
- Utilization of prescription drugs is rising rapidly as new drugs are being discovered and aggressively marketed.
- The aging of the nation's population means more people, especially those with lower incomes, will face more chronic health problems in the future.

**Reform Needed**

"There can be no more delays in addressing the TennCare problem," warned the *Commercial Appeal* in December. "The administration and the General Assembly have known the program was in a critical state for some time. They must now find the will to act, in a bipartisan fashion, and prevent the collapse of a program that was born of the best intentions and now is in critical need of reform."

The second part of the McKinsey & Company report, expected in January, will offer recommendations for making the program viable. Bredesen, who would not discuss possible TennCare reforms with *Health Care News* in advance of the consultants' report, nevertheless promised "far-reaching" solutions, rather than short-term fixes.

One immediate fix would be to drop from TennCare the 250,000 enrollees not eligible for Medicaid. Such a move would solve the problem for only a year and a half, said the governor, leaving unaddressed the underlying issue of 15 percent annual growth in TennCare costs.

The governor said he is trying to develop solutions while being "sensitive" to the fact TennCare has helped thousands of people. "I very much want to preserve it. It does help so many people. But in the end, we can't allow TennCare to bankrupt the state."

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## INTERNET INFO

See "Reforming an Ambitious State Health Care System," *Intellectual Ammunition*, July/August 2000, **http://www.heartland.org/Article.cfm?artId=170** and "Tennessee Taxpayer Revolt," *Health Care News*, August 2001, **http://www.heartland.org/Article.cfm?artId=571**.

The 38-page McKinsey & Company report, "Achieving a Critical Mission in Difficult Times — TennCare's Financial Viability," is available through *PolicyBot*. Point your Web browser to **http://www.heartland.org**, click on the *PolicyBot* button. and search for document **#14205**.
The consultants' 21-page explanation of their "Modeling Methodology and Assumptions" is also available through *PolicyBot*; search for document **#14206**.

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MY **TURN**

# A Reasonable Doubt

**by Conrad F. Meier**

Thanks to increased border security in the wake of September 11, seizures of diluted and counterfeit drugs entering the U.S. from Asia, Europe, and other locations have increased dramatically over the past two years.

American consumers seeking prescription medications at cheaper prices through unregulated storefront operations, directly from Canadian sources or over the Internet, are foolishly ignoring a reasonable doubt as to the safety of their medicines.

Elizabeth G. Durant, executive director of trade programs at the U.S. Customs Service, told the Senate Committee on Aging, "Because we are looking at more things, we are finding more things in every arena." Durant noted millions of prescriptions enter the U.S. through the mail each year as people search for lower-priced drugs.

She also noted the disturbing trend toward increasing bulk shipments of drugs, further escalating the risk counterfeit drugs could get past inspectors and find their way into the medicine cabinets of unsuspecting consumers. Customs officials are inundated by prescription drugs coming across borders, by mail or on persons who cross the border from Canada or Mexico.

**We're a Target**

A number of governors and federal legislators insist the drugs purchased in Canada are safe. They also criticize those of us who raise the "safety issue" for laying down a "smokescreen," saying we're nothing more than shills for big corporate pharmaceutical interests. If that's so, then so is Health Canada, the Canadian government's counterpart to our Department of Health and Human Services. Health Canada steadfastly refuses to vouch for the safety of drugs sold out of Canada into the U.S. How can they? Forty percent of the medicines in their drug supply don't come from Canadian sources, or even from the U.S.—they come from overseas.

**"Forty percent of the medicines in [Canada's] drug supply don't come from Canadian sources, or even from the U.S.—they come from overseas."**

America's huge market for prescription drugs is a tempting target for counterfeiters, and the growing interest in importation makes Canada an attractive port into the U.S. Louisiana Democrat Senator John Breaux, a member of the Finance Committee, said, "Counterfeiting concerns make it impossible to guarantee the safety of drugs imported from Canada or other countries."

One recent proposal to legalize importation, sponsored by Senators Byron Dorgan (D-North Dakota) and Deborah Stabenow (D-Michigan), illustrates a cavalier disregard for consumer safety. Breaux said no law could protect the chain of custody between the time the drugs leave the U.S. and the time they return. "We can guarantee that they'll be cheap," said Breaux, "but we can't guarantee that they'll be safe."

A similar proposal passed Congress and was signed into law by President Bill Clinton in 2000. The law was never implemented because of a reasonable doubt: Health officials in the Clinton and Bush administrations refuse to certify that imported drugs meet U.S. safety standards.

**More Smokescreens?**

PharmacyChecker.com, an independent research firm focused on evaluating online pharmacies and comparing prices, found 30 percent of Canadian online pharmacies surveyed had no verifiable affiliation with a licensed pharmacy.

Noted Dr. Tod Cooperman, "Six pharmacies of the 20 surveyed declined to provide information about who dispensed their drugs." He further stated it is difficult to tell whether the pharmacies are operating illegally, because some simply may not want to disclose information due to controversy on both sides of the border over online-pharmacy operations. "It is possible some Canadian Internet pharmacies may be obtaining drugs illegally from wholesalers or offshore sources," Cooperman said.

The research firm also found several Internet pharmacies didn't provide secure financial transactions online, didn't ensure privacy of information, or didn't provide reliable contact information. Only six of the 20 sites met all the firm's criteria for protecting consumer safety and privacy. All six were accredited online extensions of licensed brick-and-mortar pharmacies like Walgreens, Eckerds, and Rite-Aide.

**Health Risk**

Bogus drugs remain undetected if they do not make people obviously sick. Their effects, however, are potentially more insidious, as patients may simply fail to recover from their illnesses.

In a documented and under-reported event last year, a Michigan boy complained the growth hormone shots he was getting were giving him a burning sensation. After an analysis, it was discovered the boy was being injected with contaminated insulin. The investigators traced the mislabeled, impure product to a pharmacy in Orlando, Florida, which had purchased the product from a primary wholesaler.

Tracing back even further, it was discovered the drug previously went through three secondary wholesalers. The trail went cold at the last unlicensed wholesaler who was unable, or not required, to document where the drug came from.

Not all of the mislabeled and counterfeit insulin has been recovered. Some of it is still out there, somewhere, being injected into sick children and adults, causing pain and possibly deaths.

Anybody who thinks writing about this very real problem is just blowing smoke either isn't paying attention or is blowing smoke of his own.

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